# **EXHIBIT 2**





## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

	A TOWN	TO A STATE A PROPERTY.		ATTORNEY DOOK	-T NO
SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTORNEY DOCK	= I NO.
	/o1 1/1/01	787 KIMS	i	14014,0025	_DGP

18M2/0915

MEEDLE & ROSENBERG, P.C.SUITE 1200 THE CANDLER BUILDING 127 PEACHTREE STREET, N.E. ATLANTA GEORGIA 30303 MARSCEXAMINER

ART UNIT PAPER NUMBER

1807

SEP 23 1996

NEEDLE & ROSENBERG

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

09/18/96

DOGRETED

By: UB Date: 9-26 96

Reviewed: No dates to be docleted 06-P

## INTERFERENCE INITIAL MEMORANDI "Y

BOARD OF PATENT APPEALS /

BOARD OF PATENT AF		ERENCES: An interfere	nce is fou exist be	etween the following cases:
PARTY		FILING DATE		
KING ET A	107/110.79	1 10/21/87	PATENT NO., IF ANY	ISSUE DATE, IF ANY
If application has been patented, have **Accorded the benefit of:	maintenance fees been paid?	Yes No	Maintenance fees not	
COUNTRY	APPLICATION NO.	l	- Tallichance rees not	due yet
US	06/936/11	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
	06/836,414	3/5/87		ISSUE DATE, IF ANY
	·		<del></del>	
The claim(e) of this				
The claim(s) of this party which corresponded PATENTABLE PEND OR PATENTABLE PEND 44, 47, and	DING CLAIMS	UNPATENTABLE PENDIN	G CLAIMS	
The claims) of this party which does(do) PATENTED OR PATENTABLE PENI		):		
		UNPATENTABLE PENDING	G CLAIMS	
ARTY	APPLICATION NO.	EII DIG D		
SLAMON ET AL	06/948265	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
application has been patented, have ma		12/31/86	14,968,603	11/6/90
Accorded the benefit of:	intenance tees been paid?	YesNo	Maintenance fees not due	
UNTRY	APPLICATION NO.	FILING DATE		/
		- MAIL	PATENT NO., IF ANY	ISSUE DATE, IF ANY
	<del></del>			
			<del> </del>	
claim(s) of this party which correspond	(c) to this			
TABLE PENDIN	G CLAIMS	I DID LOTTE		
1-22		UNPATENTABLE PENDING O	CLAIMS	
claim(s) of this party which does(do) no	t correspond to this count is(are):			
TENTED OR PATENTABLE PENDIN	G CLAIMS	UNPATENTABLE PENDING C	LAIME	
TOT EVERY potent in 1	Ins	ructions		
screen 2070. Is s			hoon '11'	
35 LICC 125(2) 27 GT	nd they have not been pai	d, the interference cannot	been paid by using the	patent number with PALM
or each page 135(a); 37 CFR 1.6(	06).	TOTOLOGICO CATILIOI	be declared since it wo	patent number with PALM uld involve an expired patent
601(5) (7) I constitute pa	itentable (or patented) and	unpatentable (pending)	-1-: · · ·	1 patent
for each party, identify the pa .601(f), (n); 1.609(b)(2)).	•	r	ciaillis which correspon	d to the count (37 CFR
or cach party, identify the pa	tentable (or patented) and	unpatentable (nending)	alai t t	,,
or each party, identify the pa FR 1.609(b)(3)).	•	randore (bending) (	cialins which do not cor	respond to the count (37
				(5)
- Programme Theories Chick	e muual Memorandum an	d any attachments c	•	•
All infor	mation requested below single proposed interfere	must be set	ir records.	
n a separate sheet, set forth a	single proposed interfere	must be attached on (a)	separate typewritten s	heet(s).
LIUN LIIIIII DIRACA INDIANA AL			1 3DV ports/10 01	
r each claim designated as covention as the count (37 CF)	Orresponding to the court	number, and the claim	m number.	word for word
ention as the count (27 CE	1 cooperate to the count	provide an explanation of	of why each alaim at a	es the same notantall.
r each claim designated as no	of corresponding to the ac-	unt 11	,	me same patemanie
r each claim designated as no entable invention from the c	Ount (37 CFR 1 6000-100	ши, provide an explanati	on of why each claim de	efines a senaror
The same additional collision of the	V report at 0 /			a scharate
each additional count, if an arate patentable invention from	om every other count (27	CED 1 600 7 vide an exp	planation why each cour	1t represente o
111/21		CLK 1.609(p)(1)		robresents g
9/16/96 PRIMARY EX	AMINER (Signature)	TELEPHONE NO.		
1 Auch	4. Masshol	[703/308-	30941 ART 1	
GROUP DIREC	CTOR SIGNATURE (if required)	(10 3/ 308 2	20/-/	1807
		,		
if there are intervening analysis	application the benefit of which is i	niended to be accorded		
olication number and filing date of each of there are intervening applications ne	cessary for continuity.	and accorded must be list	ed. It is not sufficient to merely	list the earliest

Revised PTO-850 ...erference Initial Memorandum appears on the reverse side of this sheet. This form has been revised to include the changes made to the interference rules as set forth in 1173 OG 49, particularly the changes to 37 C.F.R. § 1.609.

### **HIGHLIGHTS**

#### 1. Maintenance Fees

An interference is an extremely expensive and time consuming proceeding. When a patent is to be involved in an interference, such interference can only be set up with an unexpired patent. 35 U.S.C. § 135 and 37 C.F.R. §§ 1.602, 1.606, and 1.607. Since the examiner has the initial responsibility for reviewing the interfering applications and patents, it falls within the responsibility of the Examining Group to insure that the patent in question is in fact unexpired. This requires checking if the proper maintenance fees have been timely paid. Until this is done, the files should not be forwarded for declaration of an interference. The revised form includes instructions on how to verify whether Maintenance Fees for a U.S. Patent have been paid.

- Explanation of why claims correspond to a count
- Section 1.609(b)(2) of 37 C.F.R. requires an examiner's statement explaining why each claim designated as corresponding to a count is directed to the same patentable invention as the count. The purpose of the statement is to provide the Board and the parties involved in the interference with the benefit of the examiner's reasoning while deciding whether the interference should be declared and during consideration of preliminary motions. The reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying rejections. This information must be typewritten on separate sheets of paper.
- Explanation of why claims do not correspond to a count

Section 1.609(b)(3) of 37 C.F.R. requires an examiner's statement explaining why each claim designated as not corresponding to any count is not directed to the same patentable invention as any count. As above, this statement would provide the Board and the parties involved in the interference with the benefit of the examiner's reasoning during consideration of preliminary motions. The reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying allowances. This information must be typewritten on separate sheets of

## Multiple Counts

In cases in which multiple counts are involved, 37 C.F.R. 1.609(b)(1) stipulates that the examiner must present reasons why each count is patentably distinct from the other counts. Once more, the reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying allowances. If the examiner cannot justify the patentability of one count over another count, then they must be considered as directed to the same invention and, thus, only one count would be required for the inter partes proceedings. This information must be typewritten on separate sheets of paper.

If you have any questions concerning the new form or the rule changes, feel free to contact a Program and Resource Administrator at 703-308-9797.

Interference summary for 07/110,791 versus P/N 4,968,603. Proposed phantom count: (combination of claim 44 of 07/110,791 and claim 1 of P/N 4,968,603)

A method of diagnosing or evaluating human cancer in a patient comprising: measuring the level of amplification in a tissue or tumor sample containing cells from said patient or increased expression of a MAC117 gene in a body sample from said patient, the presence of amplification or increased expression of said MAC117 gene indicating the presence of cancer or a cancer with a more malignant phenotype

OR

A method for screening patients to determine disease status, said method comprising: measuring the level of amplification or expression of the HER-2/neu gene in a sample from a patient suffering from breast or ovarian adenocarcinoma; and classifying those patients having an increased level of amplification or expression of the HER-2/neu gene relative to a reference level characteristic of normal cells as being more likely to suffer disease relapse or having a decreased chance of survival.

(Note that the Her-2/neu gene and the MAC117 gene are the same gene as summarized in P/N 4,968,603 in column 2, lines 39-43.)

All of the claims of 07/110,791 and P/N 4,968,603 correspond to the count in that they all are directed to evaluation, diagnosis, screening, or evaluation of cancer treatment as directly related procedures in that they are all based on the

analysis of the same gene regarding whether it is amplified, rearranged, or overexpressed in the tissue being tested. Such amplification, rearrangement, or overexpression being indicative of cancer diagnosis or when expressed regarding extent of gene alteration as indicative of a worsening condition of the patient whether being treated or not.

ATLIN Mashel
ARDIN H. MARSCHEL
PATENT EXAMINER
GROUP 1800